

### REMARKS

This responds to the Final Office Action dated June 5, 2007 (hereinafter “Office Action”). Claims 1-3, 6-8, 10-14, 23, 26, 29-30, 35 and 37-41 are currently amended and fully supported by the application as filed. Claim 43 is new. Claims 4, 9, 15-20, 22, 28 and 31-34 were previously or are currently cancelled without prejudice or disclaimer. Claims 8, 10-14, 27-30 and 35-42 have been previously withdrawn, but should be considered upon the allowance of generic or similar claims 1-3, 5-7, 21, 23-26 and 43 responded to below.

Applicant hereby respectfully requests further examination and reconsideration of this application in view of the foregoing claim amendments and following remarks.

#### Request for Interview

Prior to the Office issuing any subsequent communications, Applicant respectfully requests a telephonic interview at the convenience of the Examiner. Applicant’s attorney Gregory W. Smock can be reached by telephone at (612) 373-6956.

#### §112 Rejection of the Claims

1. Claim 23 was rejected under 35 USC § 112 for failing to comply with the written description requirement. Applicant has amended claim 23 to satisfy the issue noted in the Office Action. Reconsideration and withdrawal of this rejection is respectfully requested.

#### §102 Rejection of the Claims

2. Claims 1-3, 5-7 and 23-24 were rejected under 35 USC § 102(e) as being anticipated by Gardeski et al. (US Patent No. 7,130,700) (hereinafter “Gardeski”). Applicant respectfully traverses these rejections on the ground that Gardeski fails to recite each element of the claims, as amended.

#### *Claim 1:*

Claim 1 recites an implantable lead comprising, among other things, one or more fillers radially extending within an inner body surface “less than 360 degrees from a first end to a

second end.” In contrast to such claim language, Gardeski recites a cylindrical inner filler member disposable within an outer tubular member. For example, Gardeski states:

The present invention is realized by providing an elongated medical device having a generally tubular, splined inner insulating member mated with a generally tubular, splined outer insulating member.

(Gardeski at col. 5, ll. 47-50; *see also* FIGS. 1, 3-6B, 6D-6E, 8-10A, 10D and 11B-11C.)

Applicant submits that because cylindrical members are, by nature, radially continuous (i.e., extending a full 360 degrees) along a portion thereof and do not exhibit first and second radial ends, the structure of Gardeski fails to recite this claim language.

According to the Federal Circuit, “[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 200 USPQ 303, 313 (Fed. Cir. 1983). Because Gardeski does not recite one or more fillers radially extending less than 360 degrees from a first end to a second end, as recited in Applicant’s claim 1, Gardeski does not anticipate such claim. Claims 2-3, 5-7, 21, 23-27, 29 and 43 are dependent on claim 1 and are patentable over Gardeski for the reasons stated above, in addition to the elements in such claims.

*Claim 2:*

Additionally, regarding claim 2, Applicant cannot find in Gardeski any recitation of one or more filler recesses which include “non-occupied recesses, the non-occupied recesses providing compression features” to the lead. In contrast, Gardeski recites spline-occupied and conductor-occupied recesses. For example, Gardeski states:

The multilumen body is constructed from a generally tubular outer member having inward-radiating splines that mate with outward-radiating splines on a generally tubular inner member. Lumens formed between sets of mated splines isolate conductors carried therein.

(Gardeski at Abstract; *see also* col. 3, ll. 32-40 and 58-63; col. 13, l. 67 – col. 14, l. 3.)

[A] splined lead body according to the present invention may be provided having a corresponding number of mated splines for forming two, three or more lumens corresponding to the number of conductors required.

(Gardeski at col. 14, ll. 42-45.)

Because Gardeski does not recite one or more non-occupied recesses in the filler member for compression or other reasons, as recited in Applicant's claim 2, Gardeski does not anticipate such claim. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 2. Claim 3 is dependent on claim 2 and is patentable over Gardeski for the reason stated above, in addition to the elements in such claim.

*Claim 6:*

Additionally, regarding claim 6, Applicant cannot find in Gardeski any recitation of one or more fillers "generally C-shaped." In contrast, Gardeski recites a filler shape having multiple arm-like members extending outward from a central region. For example, Gardeski states:

Inner insulating member 134 includes multiple pairs of radially outward extending members 138a through 138h, each pair forming a groove or slot portion 119.

(Gardeski at col. 14, ll. 18-22.) Applicant submits that because a C-shape, by nature, does not include multiple radially outward extending members from a central region, the structure of Gardeski fails to anticipate Applicant's claimed subject matter. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 6.

*Claim 43:*

Additionally, regarding claim 43, Applicant cannot find in Gardeski any recitation of a tubular body and one or more fillers combining to form "a single isolated lumen for insertion of [ ] at lead one insulated conductor." In contrast, Gardeski recites the formation of multiple isolated lumens through the coupling of a tubular body and one or more fillers. For example, Gardeski states:

Thus, an improved multilumen body for use in elongated medical devices has been described. Numerous types of elongated medical devices requiring multiple lumens may benefit from the relative advantages of a splined multilumen body provided in accordance with the present invention, which include but are not limited to well-isolated sealed lumens.

(Gardeski at col. 19, ll. 21-27.)

Multiple lumens 140a through 140d are formed by inner insulating member 134 and outer insulating member 132, between adjacent sets of mated outward extending members 138a through 138h and inward extending members 136a through 136d.

(Gardeski at col. 14, ll. 25-29; *see also* col. 3, ll. 18-23 and 27-28; col. 6, ll. 7-10.)

Because Gardeski does not recite the combination of a tubular body and one or more fillers to form a single isolated lumen, as recited in Applicant's claim 43, Gardeski does not anticipate such claim. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 43.

3. Claims 1-3, 5-7 and 23-25 were rejected under 35 U.S.C. § 102(e) as being anticipated by Cross, Jr. et al. (US Patent No. 5,935,159) (hereinafter "Cross, Jr."). Applicant respectfully traverses these rejections on the ground that Cross, Jr. fails to recite each element of the claims, as amended.

*Claim 1:*

Claim 1 recites an implantable lead comprising, among other things, one or more fillers radially extending within an inner body surface "less than 360 degrees from a first end to a second end." In contrast to such claim language, Cross, Jr. recites a cylindrical inner filler member disposable within an outer tubular member. For example, Cross, Jr. states:

[Outer] [t]ube 100 has an inner diameter approximately equal to the outer diameter of the core 102.

(Cross, Jr. at col. 3, lns. 25-26; *see also* FIGS. 3-8 and 11-12.) Applicant submits that because cylindrical members are, by nature, radially continuous (i.e., extending a full 360 degrees) along a portion thereof and do not exhibit first and second radial ends, the structure of Cross, Jr. fails to recite this claim language.

According to the Federal Circuit, "[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 200 USPQ 303, 313 (Fed. Cir. 1983). Because Cross, Jr. does not recite one or more fillers radially extending less than 360 degrees from a first end to a second end, as recited in Applicant's claim 1, Cross, Jr. does not anticipate such claim. Claims 2-3, 5-7, 21, 23-27, 29 and 43 are dependent on claim 1 and are patentable over Cross, Jr. for the reasons stated above, in addition to the elements in such claims.

*Claim 2:*

Additionally, regarding claim 2, Applicant cannot find in Cross, Jr. any recitation of one or more filler recesses which include “non-occupied recesses, the non-occupied recesses providing compression features” to the lead. In contrast, Cross, Jr. recites conductor-occupied recesses. For example, Cross, Jr. states:

An improved lead body for implantable leads comprising a longitudinally extending core section provided with longitudinally extending grooves in which conductors are located.

(Cross, Jr. at Abstract; *see also* col. 2, ll. 52-56; col. 4, ll. 18-21; col. 5, ll. 2-4.)

This construction simplifies the manufacture of the leads, as it allows the conductor simply to be laid in the elongated grooves of the core.

(Cross, Jr. at col. 1, ll. 27-29.)

Because Cross, Jr. does not recite one or more non-occupied recesses in the filler member for compression or other reasons, as recited in Applicant’s claim 2, Cross, Jr. does not anticipate such claim. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 2. Claim 3 is dependent on claim 2 and is patentable over Cross, Jr. for the reason stated above, in addition to the elements in such claim.

*Claim 6:*

Additionally, regarding claim 6, Applicant cannot find in Cross, Jr. any recitation of one or more fillers “generally C-shaped.” In contrast, Cross, Jr. recites a filler shape having multiple arm-like portions extending outward from a central region. For example, Cross, Jr. states:

Core 102 is provided with four radially extending portions 180, 182, 184 and 186 which extend longitudinally along the length of the core, and which in turn define four longitudinally extending grooves, 190, 192, 194 and 196.

(Cross, Jr. at col. 2, ll. 35-38.) Applicant submits that because a C-shape, by nature, does not include multiple radially outward extending portions from a central region, the structure of Cross, Jr. fails to anticipate Applicant’s claimed subject matter. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 6.

*Claim 43:*

Additionally, regarding claim 43, Applicant cannot find in Cross, Jr. any recitation of a tubular body and one or more fillers combining to form “a single isolated lumen for insertion of [ ] at lead one insulated conductor.” In contrast, Cross, Jr. recites the formation of multiple isolated lumens through the coupling of a tubular body and one or more fillers. For example, Cross, Jr. states:

The outer tubing and the core together define multiple lumens in which conductors may be located.

(Cross, Jr. at col. 1, ll. 25-26.)

An outer, insulative tube 100 is shown surrounding core 102, defining four lumens in which four insulated conductors 104, 106, 108 and 110 are located.

(Cross, Jr. at col. 2, ll. 53-56.)

Because Cross, Jr. does not recite the combination of a tubular body and one or more fillers to form a single isolated lumen, as recited in Applicant’s claim 43, Cross, Jr. does not anticipate such claim. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 43.

*§103 Rejection of the Claims*

4. Claim 26 was rejected under 35 USC § 103(a) as being unpatentable over Cross, Jr. in view of Gardeski. Applicant respectfully requests reversal of this rejection on the ground that there is no *prima facie* case of obviousness.

*Claim 26:*

The proposed combination of Cross, Jr. and Gardeski is improper and fails to establish all elements recited in Applicant’s claim 26. Claim 26 recites an implantable lead in which “an outer insulation surface portion of [ ] at least one cable conductor contact[s] an outer insulation surface portion of [a] coiled conductor, such that the at least one cable conductor and the coiled conductor are electrically independent.” The Office Action admits that Cross, Jr. does not recite an outer surface portion of a cable conductor contacting an outer surface portion of a coiled conductor. (Office Action at 7.) Instead, the Office Action attempts to rely on Gardeski to

establish this missing cable-coiled conductor contacting arrangement. (*Id.*) However, Gardeski actually is directed to leads including spaced isolated conductors via insulative arm portions of a lead body filler. For example, Gardeski expressly states:

Sealing and isolating individual lumens 20a-20f is important in maintaining electrical isolation of conductors.

(Gardeski at col. 12, ll. 28-29.)

According to the present invention, each of conductors 150-156 are positioned within a respective slot portion 119 of lumens 140a-d formed by inner insulating member 134 . . . as a result, simultaneously capturing each conductor within a respective lumen.

(Gardeski at col. 15, ln. 61-col. 16, ln. 1.) Gardeski does recite an embodiment in which a pair of cable conductors are positioned within the same lumen; however, in such embodiment, the cable conductors are electrically coupled, in further contrast to Applicant's claim 26. For example, Gardeski states:

A distal segment 80 of each wire included in twisted pair 30 is stripped of insulation and extended along the distal end of sensor 42 and electrically coupled to sensor 42.

(Gardeski at col. 10, ll. 35-38; *see also* FIG. 6A.)

In other words, and in contrast to Applicant's claimed combination, Cross, Jr. in view of Gardeski recite a conductor arrangement in which an outer surface portion of a cable conductor does not contact an outer surface portion of a coiled conductor or a conductor arrangement in which two abutting cable conductors are electrically coupled. According to the Federal Circuit, motivation to combine references is lacking when the references teach away from the claimed combination. (*See Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986)(A reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered); *see also* Office Action at 2.) Because the combination of Cross, Jr. and Gardeski teach away from the Applicant's claimed combination of an outer surface portion of a cable conductor contacting an outer surface portion of a coiled conductor such that the conductors are electrically independent, the asserted combination of references is improper and fails to establish all elements recited in claim 26.

For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 26.

*Reservation of Rights*

In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action; however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, or the right to challenge or rebut any asserted factual or legal basis of any of the rejections. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any cancelled or withdrawn claims in a subsequent continuation or divisional patent application claiming the benefit of priority of the present patent application.



**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited and encouraged to telephone Applicant's attorney Gregory W. Smock at (612) 373-6956 to facilitate prosecution of this application.

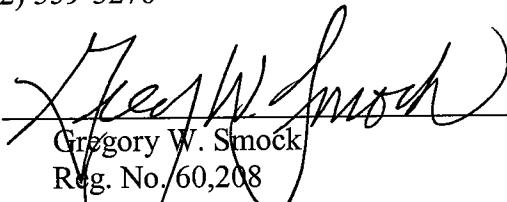
If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date DECEMBER 17, 2007

By

  
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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop RCE, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 17 day of December 2007.

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